

Notice of Allowability

Application No.

10/750,466

Examiner

Nyeemah Grazier

Applicant(s)

LEE ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/22/05.
2. ☒ The allowed claim(s) is/are 2-5.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☒ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

NOTICE OF ALLOWANCE

I. ACTION SUMMARY

Claim 1 has been canceled. Claims 2-5 are pending.

II. PRIORITY

Applicant's claim of priority to foreign application TAIWAN 92103728 filed on February 21, 2003 is acknowledged. However, the applicant has not filed an English translation as required by 35 U.S.C. § 119(b).

III. RESPONSE TO AMENDMENT/REMARKS

35 USC 103 Rejection: Applicant's amendment, canceling claim 1, renders the rejection moot. Therefore, the rejection is withdrawn.

Objection: Objection to claim 2 for minor informality, namely, typographical error, has been withdrawn because the claim has been amended to correct this error.

IV. REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The instant invention is an improved process for the manufacture of mycophenolate mofetil comprising a four step synthetic scheme that yield 99.9% purity and 89.5% yield in a reaction time of 24 hours. The process of making mycophenolate mofetil is accomplished by using (1) a transesterification reaction of the *ester derivative* of mycophenolate and 2-morpholinoethanol in the presence of a catalyst selected from the group consisting of alkaline metal salt, alkaline earth metal salt, tin

Art Unit: 1626

oxide and stannous oxide to produce the crude product. (2) Acidic aqueous solution is added to the crude material, which is then (3) basified and (4) the product is extracted from the basic solution. There is no prior art of record that anticipates or renders obvious the instant invention.

The closest prior art of record is Knox, et al., U.S. Patent No. 5,247,083 entitled "Direct Esterification of Mycophenolic Acid." Knox et al., teaches the method of synthesizing mycophenolate mofetil by refluxing for 8-200 hours mycophenolic acid (MPA) and 2-morpholinoethanol without the presence of a catalyst. The reference also teaches the same conditions with an acid or base catalyst. The prior art of reference does not teach the catalyst used in the instant invention, does not teach transesterification reaction and does not teach the four step method of the instant invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

CONCLUSION

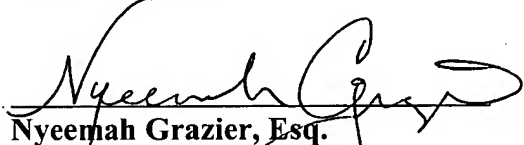
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

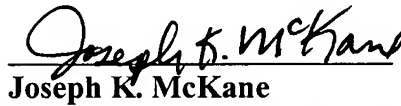
Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,



Nyeemah Grazier, Esq.
Patent Examiner, Art Unit 1626
UNITED STATES PATENT AND TRADEMARK OFFICE
400 Dulany Street
Alexandria, VA 22314-5774
Tel. No.: (571) 272-8781



Joseph K. McKane
Supervisory Primary Examiner, Art Unit 1626
UNITED STATES PATENT AND TRADEMARK OFFICE
400 Dulany Street
Alexandria, VA 22314-5774
Tel. No.: (571) 272-0699